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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,882	08/25/2003	Johannes Bartholomaus	785-011444-US(C01)	3177
7590 Clarence A. Green PERMAN & GREEN, LLP 425 Post Road Fairfield, CT 06824			EXAMINER CHOI, FRANK I	
			ART UNIT 1616	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE			MAIL DATE	DELIVERY MODE
3 MONTHS			01/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/647,882	Applicant(s) BARTHOLOMAUS ET AL.	
	Examiner Frank I. Choi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 6-8 and 13-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 9-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>20061106, 20040220, 20030825</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I in the reply filed on 11/6/2006 is acknowledged. The Applicant is correct, Group I is claims 1-37, Group II should be claim 38 and Group II is claim 39. Further, the Examiner acknowledges the election species (1RS, 2RS)-3-(3-dimethylamine-1-hydroxy-1,2-dimethylpropyl)phenol. Although, the Applicant did not indicate whether claims 1-5 read on the elected invention and species, the Examiner reads claims 1-5 as encompassing the same. This is based on the interpretation of the elected species as not being an opioid analog but within the genus of analgesic. As such, claims 1-5, 9-12 will be prosecuted to the extent they read on the elected species. Claims 6-8, 13-39 are withdrawn from consideration as directed to non-elected species.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 contains broad and narrower ranges which renders the claims indefinite as it is uncertain whether the ranges after "preferably" are merely exemplary or a required limitation of the claim.

Claim 3 contain the phrase "preferably saccharin" which renders the claim indefinite as it is uncertain whether the phrase is a required limitation or merely exemplary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 9-12 rejected under 35 U.S.C. 103(a) as being unpatentable over Dyrsting et al. (US Pat. 6,077,822) in view of WO 00/12067 and EP 0 693 475.

Dyrsting et al. disclose that it is common practice in the pharmaceutical industry to use salt forms of drugs, e.g. with physiologically acceptable organic or inorganic acids and bases such as hydrogen chloride and for drugs with amine groups it is feasible to use salts with organic or inorganic acids (Column 1, lines 15-25). It is disclosed that drugs salts with sugar acids, such as monosaccharides, exhibit increased uptake and controlled release properties and that insoluble or poorly soluble drug-sugar acid salts have to be found to have a drug release profile that is not dependent on pH in the gastrointestinal tract (Column 1, lines 35-55).

WO 00/12067 disclose that saccharinate salts of non-alkaloid organic bases provide improved organoleptic properties (page 2).

EP 0 693 475 disclose a 1-phenyl-3-dimethylaminopropane analgesic compounds of formula I, such as (1RS,2RS)-3-(3-dimethylamino-1-hydroxy-1,2-dimethylpropyl)phenol that can be converted in a known manner to their salts (Pages 5,15; See English language version - US Pat. 6,344,558, Column 5, lines 25-36, Column 15, lines 40-68).

The prior art discloses the formation of drug salts with sugars. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the

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(1RS,1RS)-3-(3-dimethylamino-1-hydroxy-1,2-dimethylpropylphenol salt with sugar. However, the prior art amply suggests the same as the prior art disclose the formulation of drug salts with sugars such as saccharinates. As such, it would have been well within the skill of one of ordinary skill in the art to prepare a (1RS,2RS)-3-(3-dimethylamino-1-hydroxy-1,2-dimethylpropylphenol salt with a sugar, such as saccharin, with the expectation that the same would be physiologically acceptable and provided improved organoleptic properties.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

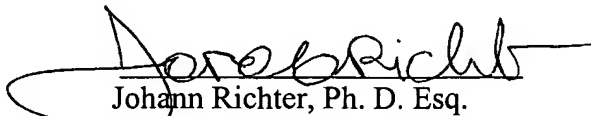
A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Dr. Johann Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
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January 22, 2007


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